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09/896,368	06/28/2001	David M. Allen	P1067	2222

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EXAMINER

PAK, JOHN D

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 07/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/896,368

Applicant(s)

Allen

Examiner

John Pak

Art Unit

1616



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jan 23, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-10, and 12-23 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration
- 5) ☒ Claim(s) 18-23 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5, 6, 8, 10, 12, 14, and 16 is/are rejected.
- 7) ☒ Claim(s) 3, 7, 9, 13, 15, and 17 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). of 1/17/02 6) ☐ Other:

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Claims 1-3, 5-10, 12-23 are pending in this application.

Claims 18-23 are allowed. Claims specific to azithromycin or PLO gel would be deemed allowable. Independent claims are suggested.

Claims 7, 9, 13, 15 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Note also that claim 15 depends on claim 13, which has been canceled.

Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 3 recites injecting the composition set forth in the method claim 1. The composition contains a "mobilizing agent in an amount sufficient to enable said macrolide antibiotic to penetrate into said sub-dermal soft tissue." This feature doesn't seem to make sense when considered in light of the injection step of claim 3. Claim 3 does not appear to further limit claim 1 in that the injection step seems to be outside the confines of requiring said mobilizing agent in said amount.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5, 6, 8, 10, 12, 14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Chemical Abstracts 100:73895.

Chemical Abstracts 100:73895 discloses an antiacne ointment that contains 1% erythromycin lactobionate in an ointment base containing hydrogel of methyl cellulose with Tween 80, cetylstearyl alcohol and triethanolamine.

Method claims 1-2, 5-6 and 8

It is recognized that the cited reference does not expressly spell out the specific steps of the method claims. However, an antiacne ointment is disclosed. An antiacne ointment is applied to acne. Acne is a subdermal soft tissue microbial infection. Therefore, the disclosure of an antiacne ointment necessarily discloses topically applying to the skin overlying subdermal soft tissue, wherein the applied ointment penetrates the subdermal soft tissue to reach the microbial infection.

Composition claims 10, 12, 14, 16 and composition features of the method claims

The claimed composition requires a macrolide antibiotic such as erythromycin, mobilizing agent to enable macrolide to penetrate into subdermal soft tissue, and optionally a penetrating enhancing adjuvant. The cited reference discloses a composition that has all three such ingredients. Erythromycin lactobionate is a erythromycin, the hydrogel of methyl cellulose falls squarely within applicant's "gel compound," and any one of Tween 80, cetylstearyl alcohol

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or triethanolamine would serve the function of a penetrating enhancing adjuvant from their solvating and surface active properties.

For these reasons, the claims are anticipated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Macy et al. (US 5,723,447).

Macy et al. disclose a sterile injectable erythromycin composition that contains vehicles such as propylene glycol monomethyl ether, dipropylene glycol monomethyl ether, diethylene glycol ethyl ether, or N-methyl pyrrolidone (see claims 1, 3, 5-6; see from column 1, line 54 to column 2, line 28). Macy et al. disclose that erythromycin is used in veterinary practice for administration by subcutaneous routes (column 1, lines 29-33).

The difference between the claims and the cited reference is that the reference does not explicitly state that the vehicles are “mobilizing agent to enable macrolide to penetrate into said sub-dermal soft tissue.” Additionally, the reference does not specifically state that the injectable formulation is for alleviating disease state resulting from microbial infection of subdermal soft

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tissue. However, the Examiner's position is that subcutaneous is the same thing as "sub-dermal" and subcutaneous administration is already known. Delivery of a well known antibiotic such as erythromycin via subcutaneous administration, i.e. injection, as suggested and taught by the reference would alleviate a disease state resulting from microbial infection of subdermal soft tissue. One having ordinary skill in the art would have been motivated to use the known subcutaneous administration of the antibiotic erythromycin for the purpose of controlling microbial infections near the locus of administration, i.e. subcutaneous/subdermal and other microbial infections. As for the "mobilizing agent," the vehicles disclosed by the reference qualify as such because of their solvating and surface active properties.


Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly suggested by the teachings of the cited reference.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Pak whose telephone number is (703) 308-4538. The Examiner can normally be reached on Monday through Friday from 7:30 AM to 4 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

  
JOHN PAK  
PRIMARY EXAMINER  
GROUP 1600